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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,684	10/27/2003	Tetsuya Suga	242791US0CONT	2064
22850	7590	03/25/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER GEORGE, KONATA M	
			ART UNIT	PAPER NUMBER
			1616	
			NOTIFICATION DATE	DELIVERY MODE
			03/25/2008	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/692,684	<b>Applicant(s)</b> SUGA ET AL.	
	<b>Examiner</b> KONATA M. GEORGE	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 12-17, 19-36, 38-46, 48-53 and 75-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 12-17, 19-36, 38-46, 48-53 and 75-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

Claims 1, 12-17, 19-36, 38-46, 48-53 and 75-78 are pending in this application.

#### ***Action Summary***

The examiner acknowledges the cancellation of claims 5, 6, 11, 54-74 and 79-90. Therefore, any and all objections and/or rejections directed to them are hereby withdrawn.

The rejection of claims 1, 12-36, 38-46, 48-53 and 75-78 under 35 U.S.C. 112, first paragraph is hereby withdrawn in view of applicants' amendment to the claims.

The rejection of claim 22 under 35 U.S.C. 112, second paragraph is hereby withdrawn in view of applicants' amendment to the claims.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1, 12-17, 19-36, 38-46, 48-53 and 75-78 are rejected under 35**

**U.S.C. 103(a) as being unpatentable over Kropf et al. (WO 00/54741) as**

**translated by Kropf et al. (US 6,858,214).**

Applicants claim a composition comprising superfine particles beta-glucan derived from water extract of a mushroom having an average particle size of 10 microns or less.

***Determination of the scope and content of the prior art***

**(MPEP §2141.01)**

Kropf et al. disclose the use of nanoscalar water-soluble  $\beta$ -glucans. The  $\beta$ -glucans are contained in cosmetic and/or pharmaceutical preparation having particle diameters in the range of 10 to 300 nm (equivalent to 0.01 to 0.30  $\mu$ m) (col. 1, lines 43-47). Column 1, lines 61-62 disclose a good source for the  $\beta$ -glucans, are yeast, from the *Sacchaomyces* family. Column 2, lines 10-37 disclose a process of producing the particles comprising dissolving the  $\beta$ -glucans under supercritical conditions in a suitable solvent, relaxing the fluid mixture through a nozzle in a vacuum, a gas or liquid, and at the same time evaporating the solvent. To prevent the particles from agglomeration the starting materials should be dissolved in the presence protective colloids or emulsifiers. The composition can further contain adjuvants known in the cosmetic and/or

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pharmaceutical industry (col. 3, lines 19-34). Column 5, lines 51-52 teach that lecithin can be used in the composition as a hyperfatting agent.

***Ascertainment of the difference between the prior art and the claims***

**(MPEP §2141.02)**

Kropf et al. do not teach that the beta-glucan particles are derived from a water extract of a mushroom.

***Finding of prima facie obviousness***

***Rational and Motivation (MPEP §2142-2143)***

Where claims are directed to a composition, the manner by which the individual components are obtained is not a patentable distinction if the resulting composition is the same as taught in the prior art. The claim is to a composition and not a method of making the composition. Therefore, any method of obtaining the beta-glucan or source of the beta-glucan would have been obvious to one of ordinary skill in the art at the time of the invention.

**Claims 1, 12-17, 19-36, 38-46, 48-53 and 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostroff et al. (US 2005/0245480).**

Applicants claim a composition comprising superfine particles beta-glucan derived from water extract of a mushroom having an average particle size of 10 microns or less.

***Determination of the scope and content of the prior art*****(MPEP §2141.01)**

Ostroff et al. disclose the use of particulate, bioavailable  $\beta$ -glucan, wherein the particle is a microparticle having a particles size of 1 micron or less (paragraphs [0009-0010]). Paragraph [0017] discloses a method of preparing the  $\beta$ -glucan particles by a method of finely grinding yeast cell walls. Paragraph [0036] discloses a process for producing  $\beta$ -glucan particles involving an extraction and purification of the alkali-insoluble  $\beta$ -glucan particles from yeast or fungal membranes. Paragraph [0030] also discusses oral anti-infective and radiochemoprotective activities of  $\beta$ -glucan derived from mushrooms and yeast.

***Ascertainment of the difference between the prior art and the claims*****(MPEP §2141.02)**

Ostroff et al. do not teach that the beta-glucan particles are derived from a water extract of a mushroom.

***Finding of prima facie obviousness******Rational and Motivation (MPEP §2142-2143)***

Where claims are directed to a composition, the manner by which the individual components are obtained is not a patentable distinction if the resulting composition is the same as taught in the prior art. The claim is to a composition and not a method of making the composition. Therefore, any method of

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obtaining the beta-glucan or source of the beta-glucan would have been obvious to one of ordinary skill in the art at the time of the invention.

### ***Conclusion***

Claims 1, 12-17, 19-36, 38-46, 48-53 and 75-78 are rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konata M. George  
Patent Examiner  
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/Johann R. Richter/  
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